REMARKS

Claims 1-15, 18-20, 23-25, 28-31, 38-40, 63-78 and 98, 99 and 101 are presently pending in the case. Claims 63 and 72 have been amended. Support for the amendments can be found throughout the specification as filed.

Reconsideration of the present case in view of the above amendments and the remarks herein is requested.

Claim rejections under judicially created doctrine of Double Patenting

The Examiner provisionally rejected claims 1-15, 18-20, 23-25, 28-31, 38-40 and 98-100 under the judicially created doctrine of double patenting as being unpatentable over claims 23-25, 27-30, 35-44 of U.S. Patent Application Serial No. 11/187,757 in view of U.S. Patent 6,395,300 to Straub et al (hereinafter Straub et al) and U.S. Patent 4,950,477 to Schmidt et al (hereinafter Schmidt et al).

Since the claims are otherwise in condition for allowance, as explained herein, Applicant requests the provisional Double Patenting rejection be withdrawn in the present case and taken up in the pending 11/187,757 case.

Since the claims have not been officially indicated as being otherwise in condition for allowance, a response to the Double Patenting rejection at this time would be premature. Therefore, the Applicant is holding such response in abeyance until such time as the claims are indicated allowable but for the Double Patenting issue.

Claim rejections under 35 USC 103(a)

The Examiner rejected claims 1-15, 18-20, 23-25, 28-31, 38-40, 63-76, 98 and 99 under 35 USC §103(a) as being unpatentable over U.S. Patent Application 2006/0159625 to Tarara et al (hereinafter Tarara et al) in view of U.S. Patent 6,395,300

to Straub et al (hereinafter Straub et al) and U.S. Patent 4,950,477 to Schmitt et al (hereinafter Schmidt et al). The rejection is traversed.

The Examiner's use of Tarara et al in rejecting claims 1-15, 18-20, 23-25, 28-31, 38-40, 63-76, 98 and 99 U.S.C. §103(a) is improper. According to 35 U.S.C. §103(c)(1), "subject matter developed by another person, which qualifies as prior art only under one or more of subsections (e), (f), and (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person." The present invention, at the time the invention was made, and Tarara et al were both owned by Nektar Therapeutics. Thus, according to 35 U.S.C. 103(c), Tarara et al cannot be used in a rejection under 35 U.S.C. §103(a). Therefore claims 1-15, 18-20, 23-25, 28-31, 38-40, 63-76, 98 and 99 are not rendered unpatentable by Tarara et al.

The Examiner states that Tarara et al qualifies as prior art under 35 U.S.C. §§102 under a subsection other than (e), (f), or (g). Applicant respectfully requests that the Examiner point out which subsection is being referred to.

The Examiner also rejected claims 1-15, 18-20, 23-25, 28-31, 38-40, 63-76, 98, 99 and 101 under 35 USC §103(a) as being unpatentable over U.S. Patent Application 2006/0177562 to Weickert et al (hereinafter Weickert et al) in view of Staub et al and Schmidt et al. The rejection is traversed.

Independent claim 1, for example, is not rendered unpatentable by Weickert et al, Staub et al and Schmidt et al. Claim 1 is to a method of providing therapy against a pulmonary fungal infection comprising, *inter alia*, administering by inhalation a powder comprising an antifungal agent, wherein the powder comprises porous particles and has a mass median aerodynamic diameter of less than about 5 microns and a bulk density of less than about 0.5 g/cm^3, the powder formulation being administered in a first dosage, followed after a predetermined time interval by a second dosage, said first

dosage being greater than the second dosage and wherein a sufficient amount of the pharmaceutical formulation is administered to maintain for at least one week a target antifungal lung concentration of at least two times a determined minimum inhibitory concentration. The references applied by the Examiner fail to teach many of these claimed features, as will be explained.

First, Weickert et al does not disclose or suggest the administration of a sufficient amount of a formulation to maintain for at least one week a target antifungal lung concentration of at least two times a determined minimum inhibitory concentration. Weickert et al only discusses daily administration and does not recognize or teach the benefits of administration in a manner that maintains the claimed level of antifungal agent for the claimed period of time. Staub et al and Schmidt et al are not relied on to make up for this deficiency.

Second, Weickert et al does not disclose or suggest the administration of a first dosage and then a second dosage less than the first dosage. Applicant has discovered a particularly useful treatment regimen. For example, as shown in Figure 3, a first dosage can be administered to achieve a target antifungal concentration in the lungs and then a second less dosage can be administered to maintain that concentration. Weickert et al does not teach such a regimen, nor does Staub et al or Schmidt et al.

Third, Weickert et al does not disclose or suggest porous particles having a mass median aerodynamic diameter of less than about 5 microns and a bulk density of less than about 0.5 g/cm^3. The Examiner attempts to make up for this deficiency by concluding that one of ordinary skill in the art would have found it obvious to use the particles taught by Staub et al in place of the particles of Weickert et al. The Examiner's conclusion is respectfully traversed. Staub et al teaches the incorporation of a porous matrix for the purpose of enhancing dissolution of a drug. Nowhere does Weickert et al teach that dissolution of a drug is an issue. Thus, one of ordinary skill in the art would not have been motivated to modify the teachings of Weickert et al to achieve an enhanced dissolution. Furthermore, if one were to enhance the dissolution of a drug, its

lung retention properties would be decreased, making it more difficult to maintain a concentration in the lungs for a one week period, as claimed. Moreover, the Staub et al particles are not disclosed to have a bulk density of less than 0.5 g/cm^3. Thus, even if one of ordinary skill in the art were to modify Weickert et al by substituting the particles of Staub et al, the resulting particles would not satisfy the limitations of claim 1.

For at least these reasons, claim 1 is not properly rejectable under 35 USC §103(a) as being unpatentable over Weickert et al, Staub et al and Schmidt et al. The modification proposed by the Examiner is not one that would have been well within the grasp of one of ordinary skill in the art at the time the invention was made. In this regard, the Examiner has failed to establish that the teachings of Staub et al and Schmidt et al could be applied, with a reasonable likelihood of success, to Weickert et al, and if they were, if the resulting combination would meet the limitations of the claim. There is no evidence to suggest that this is a situation where the ordinary artisan could have combined in the teachings in a manner that would result in the invention of claim 1 and there is no evidence to suggest the artisan would have seen the benefit in doing so. Furthermore, Applicant has unexpectedly found that by administering in the manner claimed, a more effective therapy against fungal infections can be provided. Thus, claim 1 is allowable over the references cited.

Applicant requests withdrawal of the rejection of claim 1 under 35 U.S.C. §103(a). In addition, Applicant requests withdrawal of the rejection of claims 2-15, 18-20, 63-76, 98 and 99 which depend from claim 1 and are not rendered unpatentable by Weickert et al, Staub et al, and Schmidt et al for at least the same reasons as claim 1.

Weickert et al, Staub et al and Schmidt et al do not render independent claim 23 unpatentable either. Claim 23 is to a method of providing therapy against a pulmonary fungal infection comprising an aspergillosis, the method comprising administering by inhalation directly to the lungs of a patient an aerosolized pharmaceutical formulation comprising amphotericin B, wherein the formulation comprises porous particles characterized by a mass median aerodynamic diameter of less than about 5 microns

characterized by a mass median aerodynamic diameter of less than about 5 microns and a bulk density of less than about 0.5 g/cm^3, and wherein a sufficient amount of the pharmaceutical formulation is administered to maintain for at least two weeks a target amphotericin lung concentration of at least 9 µg/g, and wherein the administration comprises a first administration period and a second administration period and wherein the amphotericin B is administered more frequently or at a higher dosage during the first administration period than during the second administration period. Weickert et al does not teach or suggest the treatment of a pulmonary infection in the manner recited. Straub et al and Schmidt et al do not make up for the deficiencies of Weickert et al. Thus, Weickert et al, Staub et al and Schmidt et al do not render claim 23 unpatentable.

For at least these reasons, claim 23 is not properly rejectable under 35 USC §103(a) as being unpatentable over Weickert et al, Staub et al and Schmidt et al. The modification proposed by the Examiner is not one that would have been well within the grasp of one of ordinary skill in the art at the time the invention was made. In this regard, the Examiner has failed to establish that the teachings of Staub et al and Schmidt et al could be applied, with a reasonable likelihood of success, to Weickert et al, and if they were if the resulting combination would meet the limitations of the claim. There is no evidence to suggest that this is a situation where the ordinary artisan could have combined in the teachings in a manner that would result in the invention of claim 23 and there is no evidence to suggest the artisan would have seen the benefit in doing so. Thus, claim 23 is allowable over the references cited.

Applicant requests withdrawal of the rejection of claim 23 under 35 U.S.C. §103(a). In addition, Applicant requests withdrawal of the rejection of claims 24, 25, 28-31, 38-40 and 101, which depend from claim 23 and are not rendered unpatentable by Weickert et al, Staub et al and Schmidt et al for at least the same reasons as claim 23.

The Examiner rejected claims 77 and 78 under 35 USC §103(a) as being unpatentable over Ponikau and Straub et al and further in view of U.S. Patent 5,854,280 to Gomez et al (hereinafter Gomez et al). Claims 77 and 78 depend from claim 63.

Claim 63 is not rendered unpatentable by Ponikau and Straub et al, as discussed above. Gomez et al does not make up for the deficiencies of Ponikau and Straub et al in rejecting claim 63. Thus, claim 63 is patentable over Ponikau, Straub et al and Gomez et al. Dependent claims 77 and 78 are also allowable over the references for at least the same reason as the claim from which they depend.

Conclusion

The claims are allowable for the reasons given above. Therefore, the Examiner is respectfully requested to reconsider the present rejections and allow the presently pending claims. Should the Examiner have any questions, the Examiner is requested to call the undersigned at the number given below.

Respectfully submitted,

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Dated: February 22, 2010

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